NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, et al., Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	CONSOLIDATED CIVIL ACTION NOS. 08-2272 & 08-1204 (JLL) **OPINION**

LINARES, District Judge.

This matter is before the Court by way of an application for claims construction by Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Pharma AG, and Novartis International Pharmaceutical Limited (collectively "Novartis") and Defendant Roxane Laboratories, Inc. ("Roxane"). The parties seek the Court's interpretation of certain language contained in the claims of United States Patent No. 5,866,581 (the "'581 Patent"). The '581 Patent is directed to a method for the treatment of postherpetic neuralgia ("PHN") in mammals, including humans.[1]

The Court held a Markman hearing on June 10, 2010. The Court has considered the parties' written and oral arguments. The Court sets forth herein its construction of the disputed

[1] The 581 Patent is contained as Exhibit A to the Opening Declaration of Richard J. Whitley, M.D. ("Whitley Decl.") submitted in support of Novartis's opening claim construction brief. The Court will cite to this Exhibit as the "581 Patent" and will include the column number and applicable line numbers for each citation.

claim terms.

I. Legal Standard

Claim construction is a matter of law to be determined solely by the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Because "[p]atent claims function to delineate the precise scope of a claimed invention and to give notice to the public, including potential competitors, of the patentee's right to exclude," a court must "construe claims with an eye toward giving effect to all of their terms." Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 781 (Fed. Cir. 2010). In construing the terms of a patent, "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the relevant art at the time of the invention." Id. at 780-81. "Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan *after reading the entire patent*." Phillips v. AWH Corp., 415 F.3d 1303, 1321 (Fed. Cir. 2005) (emphasis added). Thus, in identifying a term's ordinary meaning, "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. at 1313. In other words, the ordinary meaning is not evaluated in a vacuum divorced from the context of the claims, specification, and other intrinsic evidence. Id. at 1313, 1321 (citing Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005)). Indeed, the Federal Circuit explains that "[t]he specification is . . . the primary basis for construing the claims," and that it is "[u]sually . . . dispositive" and "is the single best guide to the meaning of a disputed term." Id. at 1315 (internal quotations omitted).

In addition to the claims and specification, a court should consult the patent's prosecution

history as it "provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. "Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id.

In construing claim terms, a district court also may examine extrinsic evidence–"all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980; see also Phillips, 415 F.3d at 1317. However, extrinsic evidence generally is viewed "as less reliable than the patent and prosecution history in determining how to read claim terms" and is "less significant than the intrinsic record in determining the legally operative meaning of claim language." Phillips, 415 F.3d at 1317-18 (internal citations omitted). For these reasons, a court should "focus[] at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition" based on extrinsic evidence. Id. at 1321. With this framework in mind, the Court now turns to the disputed claim language.

II. Discussion

The parties seek construction of various terms in Claims 1 and 15 of the '581 Patent. Claim 1 reads:

> A method for the treatment of PHN in mammals, which method comprises administering to the mammal in need of such treatment, an effective amount of famciclovir or penciclovir, or a pharmaceutically acceptable salt thereof.

(581 Patent, Col. 15:24-27.) Claim 15 reads:

> A method for the prophylactic treatment of PHN in a human in need of such treatment, which method comprises administering to said human, an effective prophylactic amount of famciclovir or penciclovir, or a pharmaceutically acceptable salt thereof.

(Id. at 16:18-22.)

A. "PHN"

Generally, PHN is a complication of herpes zoster, a condition more commonly known as shingles. (See id. at 1:60-61; Novartis's Opening Claim Constr. Br. [hereinafter "Novartis's Br."], at 1.) The parties do not dispute this general characterization. The parties also "agree that PHN is a distinct condition from acute herpes zoster, and that people who develop PHN suffer from a debilitating and often intractable pan that can last for months or even years." (Roxane's Opening Claim Constr. Br. [hereinafter "Roxane's Br."], at 2; see also 581 Patent, Col. 1:63-65.) Rather, the parties dispute when PHN begins after herpes zoster ends. Novartis proposes the following construction of the term "PHN" as used in Claims 1 and 15:

> Also known as post-herpetic neuralgia, a complication of a herpes zoster infection characterized by pain *at or after rash healing*.

(Novartis's Responsive Claim Constr. Br. [hereinafter "Novartis's Resp. Br."], at 3 (emphasis added).) Roxane, on the other hand, defines "PHN" to mean:

> The experience of pain *long (i.e., more than 4 to 6 weeks) after healing* of an acute herpes zoster virus rash.

(Id. (emphasis added).) The parties do not dispute that the "healing" referred to in the proposed constructions is the point "at which a patient had no papules, vesicles, ulcers, or crusts, and did not develop them at any later visit." (581 Patent, Col. 7:50-52.)

Roxane argues that pain up to four weeks after healing of the herpes zoster lesions continues to be herpes zoster pain. Roxane argues that its construction of "PHN" is correct because "the ordinary meaning of the term 'PHN' as understood by clinicians in the early 1990s was the experience of pain persisting more than fore to six weeks after healing of the acute herpes zoster rash." (Roxane's Br., at 11.) It further argues that "[a]bsent 'an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning.'" (Id., at 14 (citing a pre-Phillips case, York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996).) In other words, Roxane argues that, unless a patentee expressly redefines a term to depart from its ordinary meaning as it is understood in the abstract, as determined by reference to extrinsic evidence, then that "ordinary meaning" prevails. Thus, the majority of Roxane's argument and analysis begins with an examination of extrinsic evidence.

In Phillips, the Federal Circuit expressly rejected an approach that "limit[ed] the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term." 415 F.3d at 1320. The Phillips Court stated that "requiring that any definition of claim language in the specification be express . . . is inconsistent with our rulings that the specification is the single best guide to the meaning of a disputed term, and that the specification acts as a dictionary when it expressly defines terms used in the claims or *when it defines terms by implication*." Id. at 1320-21 (internal quotations omitted; emphasis added); see also Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001) ("[A] claim term may be clearly redefined without an explicit statement of redefinition.") (as quoted in Phillips). The Phillips Court further noted that "[t]he main problem with elevating the

dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." Id. at 1321.

Here, the specification contains the following statements related to the meaning of PHN:

- The effect of famciclovir on PHN (defined as pain at or after healing) was evaluated by assessing pain at 5 monthly visits after healing. (581 Patent, Col. 4:31-32.)

- [S]ome [herpes zoster] patients continue to experience pain long after healing and this is commonly referred to as postherpetic neuralgia. (Id. at 6:3-5.)

- Secondary variables included . . . duration of postherpetic neuralgia (ie, time to loss of pain after healing). (Id. at 7:47-50.)

- Postherpetic neuralgia has been defined in relationship to acute zoster onset, at time points ranging from one to six months after zoster rash appears, and in relationship to healing of zoster lesions, as was done in the current study. (Id. at 10:34-38 (internal citations omitted).)

All of these statements were made in the sections of the specification discussing a clinical study involving the use of famciclovir. It should be noted, however, that this study was the only study discussed in detail in the specification and comprised a significant portion of the specification; other studies were noted only by reference in relation to the primary study or by citation. In addition to these statements in the specification, the prosecution history contains the following statement by the Examiner distinguishing the prior art from the '581 patent:

> The poster citation from ICAAC presented by Dr. Patrick Gheeraert teaches the administration of famciclovir, a derivative of penciclovir, for the treatment of pain during an active outbreak of herpes [zoster] viral lesions and throughout various stages various stages of lesion healing. The disclosed graphs show the efficacy of famciclovir with respect to time to loss of pain. Gheeraert does not teach or suggest the administration of famciclovir or penciclovir in methods for the treatment of *postherpetic neuralgia after healing of the zoster lesion* or for the prophylactic treatment of postherpetic neuralgia.

(Decl. of Dr. Donald H. Gilden [hereinafter "Gilden Decl."], Ex. 16, 581 Patent Prosecution Hist., at ROX00050348 (italics emphasis added).)

Novartis argues that PHN is expressly defined in the patent as pain at or after healing, referring primarily to the first specification excerpt highlighted above. Roxane argues that this statement is insufficient to act as an express definition in the patent. The Court need not answer that question because it finds that the term PHN is defined in the specification at least by implication.

First, the clinical study discussed in the specification clearly used a definition of PHN which is the same as or similar to the one Novartis proposes. And, although the discussion related to the clinical study does acknowledge other definitions of PHN, including one encompassing Roxane's proposed definition, it expressly states that those other definitions were not used for the study. Additionally, while the specification may contain references to articles and other studies that used the definition proposed by Roxane, Roxane's proposed definition is never adopted in the specification's discussion. Thus, Roxane's proposed definition of "PHN" is contrary to the only way that the term was expressly used in the specification. Second, the Examiner's statement in the prosecution history refers to a period for the treatment of PHN "after healing of the zoster lesion." The statement does not specify or state that any time lag is required after healing for the '581 patent to be differentiated from the prior art, which dealt with methods for the treatment of pain "during an active outbreak of herpes [zoster] viral lesions and throughout various stages various stages of lesion healing," i.e. before healing. Third, Roxane's expert, Dr. Gilden, testified that the "definition of 'PHN' as defined in this patent" was "pain at or after healing." (Gilden Dep. Tr. 101:4-20.) Fourth, the extrinsic evidence submitted does not

support a finding that there was a common meaning of PHN even in the abstract. The specification noted that, in 1993 or before, the relevant period for construction of the '581 patent, the definition of postherpetic neuralgia varied between studies. Roxane's expert, Dr. Gilden, agreed that there was not one and only one ordinary meaning of PHN in 1993. (See id. at 98:2-11.) The extrinsic evidence submitted by the parties indicates that PHN was defined by some as including pain at anytime after healing. (See, e.g., Whitley Decl., Ex. B, Schmader et al., Are Current Therapies Useful for the Prevention of Postherpetic Neuralgia?, *J. Gen. Intern. Med.* (1989), at ROX00050264 ("We suggest defining PHN as pain after the skin has healed. This definition eliminates confusion with discomfort from cutaneous lesions and avoids choosing an arbitrary point in time at which to call zoster neuralgia 'postherpetic.'").) Thus, a definition for PHN of pain after healing was not novel in 1993.

But, while the Court finds that PHN has been defined at least by implication in the specification, it does not agree with Novartis that the definition is properly construed as "at or after healing" versus simply "after healing," as was more consistently used in the specification and as used by the Examiner. Novartis argues that the distinction between the two phrases is inconsequential because healing is a split second in time. Novartis argues that the addition of the word "at" in the definition "emphasize[s] that PHN includes pain that persists at healing, as well as any pain that may later develop in persons who are pain-free at healing." (Novartis's Resp. Br., at 13.) The Court finds the addition of the word "at" to be unnecessary and not as consistent with the intrinsic evidence as a whole. The word "after" captures pain at any point after healing. Whether the pain persisted or whether it had ceased and recurred, either would be pain after healing and would be considered PHN. Therefore, the Court construes the term "PHN" as used

in Claims 1 and 15 to mean: Also known as post-herpetic neuralgia, a complication of a herpes zoster infection characterized by pain after rash healing.

B. "Treatment of PHN"

Novartis proposes the following construction of the term "treatment of PHN" as used in Claim 1:

> Achieving a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

(Id., at 3.) Roxane, on the other hand, defines "treatment of PHN" as used in Claim 1 to mean:

> Achieving a therapeutic effect on PHN in mammals, for example, by reducing the duration and/or incidence of PHN when compared to a control.

(Id.) The definitions differ in two respects. First, Roxane's definition includes reducing the incidence of PHN. Second, Roxane's definition includes only those treatments that have a therapeutic effect as compared to a control, including an active control.

With respect to the first difference, the Court finds that Roxane's construction has no support in the intrinsic evidence. Although the patent states that "'treatment' includes prophylaxis as appropriate," (581 Patent, Col. 1:11-12), it does not further define prophylaxis to mean prevention of disease. On the contrary, in the background of the invention section, the patent expressly states that "[t]here is currently no proven therapy for preventing PHN." (Id. at 2:1.) The specification further states that, as such, "there is a need for therapy which alleviates or shortens the *duration* of post-herpetic neuralgia." (Id. at 2, 4-5 (emphasis added).) Additionally, the study highlighted in the specification repeatedly notes the effect of famciclovir on the duration of PHN. (See, e.g., id. at 9:13-15 ("[F]amciclovir . . . significantly reduced the duration of postherpetic neuralgia."); id. at 10:46-48 ([F]amciclovir clearly demonstrated a significant

reduction in the duration of postherpetic neuralgia in comparison with placebo.").) For its proposed construction, Roxane relies heavily on the "ordinary meaning" of the word treatment as defined in various dictionary and treatises. But, as discussed above, a term may not be given a meaning based on extrinsic evidence viewed in the abstract without reference to the context provided by the specification and other intrinsic evidence. Therefore, the Court rejects Roxane's inclusion of the word incidence in the definition.

The Court also agrees with Novartis that, given the intrinsic evidence, the effect should be compared to any treatment versus only to a control. The study primary highlighted in the specification evaluated the effect of famciclovir as compared to a placebo. (See id. at 10:46-48.) Although that study referenced another study using an active control, the focus of the '581 patent, read as a whole, is on the effect of famciclovir over any other treatment. There is nothing in the intrinsic evidence or in the meaning of "treatment," as defined in extrinsic evidence, that supports a finding that "treatment" only includes a course of therapy that is better than every alternative. Therefore, the Court construes the term "treatment" in Claim 1 to mean: Achieving a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

C. "Prophylactic Treatment of PHN"

Novartis proposes the following construction of the term "prophylactic treatment of PHN" as used in Claim 15:

> Achieving, by preventative measures (i.e., before PHN manifests itself), a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

(Novartis's Resp. Br., at 4.) Roxane, on the other hand, defines "prophylactic treatment of PHN"

as used in Claim 15 to mean:

> Preventing PHN in humans who would otherwise develop PHN when compared to a control.

(Id.) In addition to the two differences discussed above for the term "treatment of PHN" in Claim 1, the parties also differ on whether prophylactic in this term means "by preventative measure" or "preventing PHN." Roxane argues that the plain meaning of prophylactic, as defined using extrinsic evidence, is something that is preventative. It also argues that Novartis's construction of the term "prophylactic treatment of PHN" is inappropriate because it would render the word "prophylactic" superfluous, resulting in Claims 1 and 15 having the same scope. See Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1381 (Fed. Cir. 2006) (noting that a claim generally should not be construed in a way that "would render additional, or different, language in another independent claim superfluous"). As the Court noted above, there is no support in the specification or other intrinsic evidence that the claimed methods are aimed at preventing PHN. The specification expressly states that there is no proven therapy for preventing PHN. Thus, the term prophylactic as used in Claim 15 should not be so construed. In fact, Roxane's expert, Dr. Gilden, testified that "prophylactic treatment" could mean "anything that would impact on the disease in advance," such as a treatment that would lessen "the severity or duration" of a disease. (Gilden Dep. Tr. 130:2-11.) The Court also disagrees with Roxane that Novartis's construction renders Claims 1 and 15 of identical scope. While Claim 1 encompasses preventative measures, its scope is not limited to such measures. Claim 1 is broad enough also to encompass treatment after PHN manifests itself, subject to the limitations identified below with regard to the other disputed terms. For these reasons, the Court construes

the term "prophylactic treatment" in Claim 15 to mean: Achieving, by preventative measures (i.e., before PHN manifests itself), a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

D. "Mammal in Need of Such Treatment"

Novartis proposes the following construction of the term "mammal in need of such treatment" as used in Claim 1:

> A mammal prone to develop PHN and for whom there is a recognized need for the treatment of PHN.

(Novartis's Resp. Br., at 4.) Roxane, on the other hand, defines "mammal in need of such treatment" as used in Claim 1 to mean:

> A mammal diagnosed with PHN.

(Id.) Roxane argues that the "need for treatment of PHN can only be deemed necessary when a medical professional has diagnosed the subject as having PHN." (Roxane's Br., at 21.) It is undisputed that PHN cannot be diagnosed during acute herpes zoster since PHN, as defined above, only occurs if pain persists or occurs after healing. Dr. Gilden, Roxane's expert, agreed. (Gilden Dep. Tr. 67:11-13.) Additionally, Claims 2 and 3 of the '581 patent describe methods "wherein the treatment is within 72 [and 48] hours of [herpes zoster] rash onset," respectively. (581 patent, Col. 15:28-31.) In the summary of the invention section, the specification also states that "[i]t has now been discovered that the above compounds are particularly effective in reducing the duration of PHN *when given to the patient during the acute infection*." (Id. at 2:8-10 (emphasis added).) Indeed, the specification states that "[t]he treatment is preferably carried out as soon as possible after symptoms appear usually within 72 hours, preferably within 48

hours of rash onset." (Id. at 3:45-47.) Thus, if "in need of such treatment" is construed as proposed by Roxane, the construction would exclude two claims and the preferred method of treatment identified in the specification. Such a construction is presumptively incorrect. See OSRAM GmbH v. ITC, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

Roxane argues that "the Examiner plainly understood that the independent claims require 'the administration of famciclovir or penciclovir . . . after healing of the zoster legion." (Roxane's Responsive Claim Constr. Br. [hereinafter "Roxane's resp. Br."], at 9 n.3.) This redacted quote is misleading. The Examiner stated, in full, that "Gheeraert does not teach or suggest the administration of famciclovir or penciclovir in methods for the treatment of postherpetic neuralgia after healing of the zoster lesion or for the prophylactic treatment of postherpetic neuralgia." (Gilden Decl., Ex. 16, at ROX00050348.) The Examiner did not say that the administration of the drug was after healing. Additionally, the Examiner noted that the prior art did not include prophylactic treatment of PHN, which occurs prior to manifestation of the disease. Dr. Gilden, Roxane's expert, also testified that "Claim 1 doesn't require a diagnosis of postherpetic neuralgia like in the ordinary sense." (Gilden Dep. Tr. 120:10-20.)

Additionally, neither case relied on by Roxane, Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (Fed. Cir. 2003), or Schering Corp. v. Glenmark Pharm. Inc., No. 07-1334, 2008 WL 4307189 (D.N.J. Sept. 16, 2008), supports Roxane's construction. First, regardless of the construction given to a term in other cases, the term in this case must be evaluated in the context of the patent at issue here. Second, neither case stands for the proposition that the term "in need of" *requires* a diagnosis. These cases construed "in need of" to require only that the need be "recognized and appreciated," Jansen, 342 F.3d at 1334, or that there be "an appreciation for the

purpose of the drug," Schering, 2008 WL 4307189, at *9. Thus, the Court does not find that the interpretations in these cases supports Roxane's proposed construction.

Roxane also argues that its construction comports with good medical practice because "a physician cannot prescribe a drug for a particular condition unless he or she first makes a diagnosis that the patient actually has the condition." (Roxane's Resp. Br., at 10.) At the June 10 hearing, the Court pressed Roxane's counsel on this point, and its counsel would not concede that it was appropriate to prescribe a medication where a patient did not presently have the actual condition sought to be addressed by the treatment–i.e., the patient had not been diagnosed with the condition. (See Hearing Tr. 93:25-99:25.) Aside from the fact that the basis for its construction centers on extrinsic evidence considered without reference to the patent, the Court finds this argument to be contrary to common sense. For example, if a person is bitten by a wild raccoon, and the animal is not caught, doctors may give rabies shots to the person even though the person does not presently have rabies because that person would be considered at risk of developing rabies. Finally, while the Court understands Roxane's argument that the '581 patent must be differentiated from prior art, it disagrees that a definition may be adopted that is directly contrary to the intrinsic evidence. For these reasons, the Court rejects Roxane's proposed construction. This does not mean, however, that the Court agrees that Novartis's construction as proposed is appropriate.

Novartis agrees that the need for treatment must be recognized and appreciated. It argues that its definition, which requires that the mammal be one who is "prone to develop PHN and for whom there is a recognized need for the treatment," adequately limits Claim 1 to those mammals with a recognized need for treatment for PHN, as treatment has been defined above. Roxane, on

the other hand, argues that the "prone to develop" limitation was "fashioned from whole cloth" and is inappropriately indefinite. (Roxane's Resp. Br., at 11-12.) Novartis argues that the term prone is not indefinite. Novartis argues that, if a patient "fall[s] into at least one high-risk group, a [person of ordinary skill in the art] would consider [the] patient[] prone to develop PHN and would recognize [him] as 'in need' of treatment for PHN." (Novartis's Resp. Br., 27.) In response, Roxane points out that the only risk factor addressed in the specification is age. The Court agrees that age is mentioned numerous times in the specification as a risk factor for developing PHN. (See, e.g., 581 Patent, Col. 1:65-67 ("Although rare in patients under 50 years of age, the frequency of PHN rises steeply with increasing age."); id. at 10:9-11 ("those patients most at risk of developing postherpetic neuralgia (eg, elderly)").) But, it disagrees that a claim must be narrowed in scope to only those factors explicitly identified in the specification. See Silicon Graphics, Inc. v. ATI Techs., Inc, 607 F.3d 784, 792 (Fed. Cir. 2010) (A construing court's reliance on the specification must not go so far as to import limitations into claims from examples or embodiments appearing only in a patent's written description . . . unless the specification makes clear that the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.") (internal quotations omitted); Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("[E]ven where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.").

Given that the term "in need of" was included in Claim 1 and that the specification precludes a finding that a diagnosis is always required, the Court finds that the intrinsic evidence

implies that there must be some way, other than diagnosis, for the need to be recognized. The specification does discuss risk factors, albeit focusing on age. The Court agrees with Novartis that the presence of high risk factors in a mammal with acute herpes zoster sufficiently limits Claim 1 to those mammals with a recognized and appreciated need, and that this construction is consistent with the intrinsic evidence. A person of skill in the art in 1993 could recognize high risk factors for PHN. (See, e.g., Whitley Decl., Ex. B, at ROX00050270 (identifying age and extensive rash as risk factors) & Ex. D, at 748 (identifying age and severe initial neuralgia as risk factors).[2]) In other words, Novartis argues, and this Court agrees, that a mammal at high risk objectively could be considered at high risk to develop PHN and, thus, could be recognized by a person of skill in the art as being in need of treatment for PHN. This construction also is consistent with, but sufficiently differentiated from, dependent claims 5, 6, and 7 in the '581 patent, which address only age.

But, the Court also finds that Novartis's proposed construction is more limited than appropriate, given the intrinsic evidence, in that Novartis's proposed definition *requires* proneness. Although the patent focuses on treatment methods administered during an acute herpes zoster outbreak, as noted above, Claim 1 is not limited to such treatments. It is possible, under a reasonable interpretation of Claim 1, that treatment could occur after PHN has manifested itself. In fact, Claim 15 is limited to prophylactic treatment, implying that Claim 1 is

---

[2] Roxane argues that some of these extrinsic materials cannot be used to support Novartis's construction because the authors used a different *temporal* definition of PHN than the one used by Novartis. (See Roxane's Resp. Br., at 12 n.5.) But, someone at risk of developing PHN four weeks after rash healing is still at risk for developing PHN using Novartis's definition. Thus, the Court finds Roxane's argument unpersuasive. Factors other than age were identified as risk factors for developing PHN prior to 1993.

not of such a limited scope. Therefore, the Court construes the term "mammal in need of such treatment" in Claim 1 to mean: A mammal with acute herpes zoster who is at high risk of developing PHN, for example, the elderly, or a mammal who has been diagnosed with PHN.

E. "Human in Need of Such Treatment"

Novartis proposes the following construction of the term "human in need of such treatment" as used in Claim 15:

> A human prone to develop PHN and for whom there is a recognized need for the prophylactic treatment of PHN.

(Novartis's Resp. Br., at 5.) Roxane, on the other hand, defines "human in need of such treatment" as used in Claim 15 to mean:

> A human diagnosed with PHN.

(Id.) The only difference between these proposed constructions and those in the previous section is that Claim 15 is limited to prophylactic treatment, which this Court has interpreted, in the context of the '581 patent, to mean treatment involving preventative measures administered before PHN manifests itself. Thus, because a diagnosis is not possible before PHN manifests itself, this term in Claim 15 cannot reasonably include humans diagnosed with PHN as proposed by Roxane. Therefore, for this reason and those discussed in the previous section, the Court construes the term "human in need of such treatment" in Claim 15 to mean: A human with acute herpes zoster who is at high risk of developing PHN, for example, the elderly.

F. "Effective Amount"

Novartis proposes the following construction of the term "effective amount" as used in Claim 1:

> An amount effective for the treatment of PHN in the mammal in need of such treatment.

(Id., at 4.) Roxane, on the other hand, defines "effective amount" as used in Claim 1 to mean:

> 50 mg to 1 g of the active ingredient, administered in doses one to four times daily.

(Id.) Novartis argues that Roxane's proposed construction includes a dosage range identified in the patent as but one possible range. Thus, Novartis argues that Roxane's construction would include ineffective amounts and exclude effective amounts. The specification states:

> An amount effective to treat the virus infection depends on the nature and severity of the infection and the weight of the mammal. A suitable dosage unit *might contain* from 50 mg to 1 g of active ingredient, for example 100 to 500 mg. Such doses may be administered 1 to 4 times a day or more usually 2 or 3 times a day. The effective dose of a compound will, in general, be in the range of from .2 to 40 mg per kilogram of body weight per day or, more usually, 10 to 20 mg/kg per day in the case of famciclovir, the dosage unit would be 250 mg, 500 mg or 750 mg, preferably 250 mg or 500 mg.

(581 Patent, Col. 3:33-44 (emphasis added).) The Court agrees that the specification does not limit the dosage range to the one proposed by Roxane. However, the Court also finds that Novartis's mere switching of the words "effective amount" by itself is insufficient as a construction of the term. Therefore, the Court construes the term "effective amount" in Claim 1 to mean: An amount effective for the treatment of PHN in the mammal in need of such treatment, depending on the severity of the infection and the weight of the mammal and which usually will be in the range of from .2 to 40 mg per kilogram of body weight per day.

G. "Effective Prophylactic Amount"

Novartis proposes the following construction of the term "effective prophylactic amount" Claim 15:

> An amount effective for the prophylactic treatment of PHN in the human in need of such treatment.

(Novartis's Resp. Br., at 5.) Roxane, on the other hand, defines "effective prophylactic amount" Claim 15 to mean:

> 50 mg to 1 g of the active ingredient, administered in doses one to four times daily.

(Id., at 4.) Roxane makes no arguments for this term separate from those it made for the term "effective amount" in Claim 1. Therefore, for the reasons identified in the previous section, the Court construes the term "effective prophylactic amount" in claim 15 to mean: An amount effective for the prophylactic treatment of PHN in the human in need of such treatment, depending on the severity of infection and the weight of the human and which usually will be in the range of from .2 to 40 mg per kilogram of body weight per day.

H. "A Method for the Treatment of PHN"

The parties did not identify this phrase as one in need of construction in the opening briefs. Rather, they broadly addressed a requirement of intent to treat PHN inherent in Claim 1. Based on Roxane's arguments in its opening brief, Novartis addressed construction of this phrase in its reply brief. Because the arguments related to this phrase address the broader intention arguments posed by both parties throughout their papers, the Court will construe this phrase. Novartis proposes the following construction of the phrase "a method for the treatment of PHN" as used in Claim 1:

> [A] method performed for the purpose of achieving a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

(Id., at 35.) Roxane, on the other hand, proposes that this term be construed to mean:

> [A] method efficacious for the reduction in duration and/or incidence of PHN, wherein PHN is defined as above to exclude the prior art treatment of acute herpes zoster pain.

(Id., at 35-36.) Both parties agree that Claim 1 "require[s] that the method be performed with the intention of treating PHN" rather than acute herpes zoster." (Id., at 4.) But, Roxane argues that "a diagnosis of PHN and a prescription of famciclovir to treat that condition" is required in order to distinguish the '581 patent from the prior art. (Roxane's Resp. Br., at 14.) This patent differentiation argument is at the core of all of Roxane's claim construction arguments. Roxane argues that, unless there is some objective way to know that a mammal is being treated for PHN as opposed to herpes zoster, then the '581 patent will involve treatment methods that overlap with prior art. In other words, Roxane argues that the '581 patent must *exclude* methods which treat herpes zoster.

But, as Novartis points out, the '581 patent noted that the clinical trial "found that the administration of famciclovir during the acute infection reduced the duration *of acute pain* in patients with severe rash . . . in addition to reducing their duration of PHN." (Novartis's Resp. Br., at 37 (emphasis added); see also 581 Patent, Col. 9:57-62.) Thus, Novartis argues that "a POSA [reading the '581 patent] would reasonably expect that the claimed method of treating PHN may also positively impact acute herpes zoster pain." (Novartis's Resp. Br., at 37.) Additionally, as discussed above, importing into Claim 1 a requirement for a diagnosis of PHN prior to any treatment in order to signify an intention to treat PHN is directly contrary to claims 2 and 3 and the specification as a whole. Although a court generally should construe claims to support validity, a court "may not redraft claims, whether to make them operable or to sustain their validity" where they "are susceptible to only one reasonable interpretation." Chef Am., Inc.

v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004); see also Haemonetics, 607 F.3d at 781. The Court finds Roxane's proposed construction to be unreasonable.

The Court finds that the purpose or intent to treat PHN appropriately is captured by the combination of phrases "treatment of PHN" and "mammal in need of such treatment" and the limitations those terms have been construed to impose. Therefore, for these reasons and those discussed above regarding construction of the other terms at issue, the Court agrees with Novartis that the intention required in Claim 1 is that the method be performed for the purpose of achieving a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment, as evidenced by adherence to the treatment methods and as limited by the other construed terms.

I. "A Method for the Prophylactic Treatment of PHN"

Novartis proposes the following construction of the phrase "a method for the treatment of PHN" as used in Claim 15:

> [A] method performed for the purpose of achieving, by preventive measures (i.e., before PHN manifests itself), a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

(Novartis's Resp. Br., at 38.) Roxane, on the other hand, proposed that this term be construed to mean:

> [A] method efficacious for preventing (reducing the incidence of) PHN, wherein PHN is defined as above to exclude the prior art treatment of acute herpes zoster pain.

(Id., at 39.) For the reasons discussed in the prior section, the Court agrees that Novartis's proposal is the appropriate construction of the intention required in Claim 15.

III. Conclusion

For the aforementioned reasons, the Court construes the disputed terms of the '581 Patent as detailed above. An appropriate Order accompanies this Opinion.

Dated: September 17, 2010

/s/ Jose L. Linares
United States District Judge